

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA

RECEIVED

CLIFFORD BAILY, CLIFFORD BLACK,)
WESLEY CALHOUN, CURTIS DEASON,)
RUTH GRAVES, MICKEY GRIZZARD,)
JIMMY PERRY, HERBERT STANLEY SIKES,)
And PHILLIP THOMPSON,)

Plaintiffs,)

vs.)

MERCK & CO., INC., a foreign or)
Domestic Corporation, DAVID SPARKMAN,)
KATHERINE HOLMES, LORI LOVETT,)
SCOTT BARTLETT, CORAL HARPER,)
MELISSA SANTIAGO, HENRY MITCHAM,)
JERRY PHARR, JASON DELK, CHARLES)
HENDERSON, JAMES HOUSTON, JULIE)
MELTON, JULIE HODGES, MELISSA)
BAUER, NATASHA WALKER-MCGLOTHAM)
RANDY WELLS, and the Defendants A,)
B, C, D, E, X & Z whether singular or)
plural, being those persons, firms or)
entities who or which proximately)
caused or contributed to the Plaintiff's)
and Plaintiff's decedent's other harm)
and the other damages as complained)
of herein whose true names are)
unknown to the Plaintiff but will be)
added by amendment when correctly)
ascertained,)

Defendants.)

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DEBRA P. HACKETT, CLK
U.S. DISTRICT COURT
MIDDLE DISTRICT ALA

CASE NUMBER: CV-

3:06CV979-M
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Removed from the
Circuit Court of
Randolph County, Alabama
(CV-06-145)

ANSWER OF DEFENDANT MERCK & CO., INC.

COMES NOW, Defendant Merck & Co., Inc. ("Merck"), by its and through undersigned attorneys, hereby answers the Complaint ("Complaint") as follows:

Response to “GENERAL AND JURISDICTIONAL ALLEGATIONS”

1. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in this paragraph except that, to the extent Plaintiffs allege any causal relationship between the prescription medicine Vioxx® and any injury to the Plaintiffs or their decedent, Merck denies those allegations. Merck admits that it is authorized to do business in Alabama. Merck further admits that it manufactured, marketed and distributed the prescription medicine Vioxx and that it marketed and distributed Vioxx in Alabama. Otherwise, Merck denies each and every allegation contained in paragraph 1 of the Complaint.

2. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in this paragraph except that, to the extent Plaintiffs allege any causal relationship between the prescription medicine Vioxx and any injury to the Plaintiffs or their decedent, Merck denies those allegations. Merck admits that it is a New Jersey corporation with its principal place of business in New Jersey and that it is authorized to do business in Alabama. Merck further admits that it manufactured, marketed and distributed the prescription medicine Vioxx and that it marketed and distributed Vioxx in Alabama. Otherwise, Merck denies each and every allegation contained in paragraph 2 of the Complaint.

3. Merck denies each and every allegation contained in paragraph 3 of the Complaint.

4. Merck denies each and every allegation contained in paragraph 4 of the Complaint.

5. Merck denies each and every allegation contained in paragraph 5 of the Complaint except admits that Plaintiffs bring this action and purport to seek monetary damages but denies that there is any legal or factual basis for such relief.

Response to "PARTIES TO THIS CIVIL ACTION"

6. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in paragraph 6 except that, to the extent Plaintiffs allege any causal relationship between the prescription medicine Vioxx and any injury to the Plaintiffs or their decedent, Merck denies those allegations. Otherwise, Merck denies each and every allegation contained in paragraph 6 of the Complaint.

7. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in this paragraph except that, to the extent Plaintiffs allege any causal relationship between the prescription medicine Vioxx and any injury to the Plaintiffs or their decedent, Merck denies those allegations. Otherwise, Merck denies each and every allegation contained in paragraph 7 of the Complaint.

8. Merck denies each and every allegation contained in this paragraph of the Complaint except that it admits it is a New Jersey corporation with its principal place of business in New Jersey and that it is authorized to do business in Alabama. Merck further admits that it manufactured, marketed and distributed the prescription medicine Vioxx and that it marketed and distributed Vioxx in Alabama. Otherwise, Merck denies each and every allegation contained in paragraph 8 of the Complaint.

9. Merck states that the allegations contained in paragraph 9 of the Complaint are not directed at Merck and therefore no response is required. Should a response be deemed

required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 9 of the Complaint.

10. Merck states that the allegations contained in paragraph 10 of the Complaint are not directed at Merck and therefore no response is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the fictitious pleadings contained in paragraph 10 of the Complaint.

11. Merck states that the allegations contained in paragraph 11 of the Complaint are not directed at Merck and therefore no response is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the fictitious pleadings contained in paragraph 11 of the Complaint.

12. Merck admits that it manufactured, marketed and distributed the prescription medicine Vioxx and that it marketed and distributed Vioxx in Alabama. Merck objects to Plaintiffs' use of the term "Defendant" to refer collectively to all named and/or fictitious Defendants in this action and, to the extent that Plaintiffs allege that Merck is jointly and severally liable for damages for any alleged injury to their decedent or themselves, Merck denies the allegations contained in this paragraph.

Response to "JURISDICTION AND VENUE"

13. The allegations contained in paragraph 13 are legal conclusions as to which no responsive pleading is required. If a response is required, Merck denies the allegations made in this paragraph of the Complaint.

14. The allegations contained in the first sentence of paragraph 14 regarding venue are legal conclusions as to which no responsive pleading is required. If a response is required, Merck denies the allegations made in this paragraph of the Complaint.

Response to "FACTUAL ALLEGATIONS"

15. Merck denies each and every allegation set forth in paragraph 15 of the Complaint and avers that Vioxx is the brand name for rofecoxib. Merck respectfully refers the Court to the relevant United States Food and Drug Administration ("FDA")-approved prescribing information for Vioxx for its indicated uses.

16. Merck denies each and every allegation contained in paragraph 16 of the Complaint except admits that Vioxx is part of a class of drugs known as NSAIDs and that Merck manufactured, marketed, and distributed the prescription medicine Vioxx which reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2).

17. Merck denies each and every allegation contained in paragraph 17 of the Complaint.

18. Merck denies each and every allegation contained in paragraph 18 of the Complaint except admits that Vioxx is part of a class of drugs known as NSAIDs and that Merck manufactured, marketed, and distributed the prescription medicine Vioxx which reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2).

19. Merck states that the allegations contained in paragraph 19 of the Complaint are not directed at Merck and therefore no response is required. Should a response be deemed required, Merck denies each and every allegation contained in this paragraph of the Complaint.

20. Merck denies each and every allegation contained in paragraph 20 of the Complaint except admits that Vioxx is part of a class of drugs known as NSAIDs and that Merck manufactured, marketed, and distributed the prescription medicine Vioxx which reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2).

21. Merck denies each and every allegation contained in paragraph 21 of the Complaint and further avers that the studies referenced therein speak for themselves.

22. Merck denies each and every allegation contained in paragraph 22 of the Complaint and further avers that the studies referenced therein speak for themselves.

23. Merck denies each and every allegation contained in paragraph 23 of the Complaint and further avers that the studies referenced therein speak for themselves.

24. Merck denies each and every allegation contained in paragraph 24 of the Complaint and further avers that the studies referenced therein speak for themselves.

25. Merck denies each and every allegation contained in paragraph 25 of the Complaint and further avers that the press release referenced therein speaks for itself.

26. Merck denies each and every allegation contained in paragraph 26 of the Complaint and further avers the letters referenced therein speaks for themselves.

27. Merck denies each and every allegation set forth in paragraph 27 of the Complaint, except that it admits that the studies and article referenced in this paragraph exist, and respectfully refers the Court to said publications for their actual language and full text. Merck further admits that it is currently a member of the European League Against Rheumatism ("EULAR") and that it has been a sponsor of EULAR since 1999.

28. Merck denies each and every allegation contained in paragraph 28 of the Complaint and further avers that the studies referenced therein speak for themselves.

29. Merck denies each and every allegation contained in paragraph 29 of the Complaint and further avers that the website referenced therein speak for itself.

30. Merck denies each and every allegation contained in paragraph 30 of the Complaint.

31. Merck denies each and every allegation contained in paragraph 31 of the Complaint.

32. Merck denies each and every allegation contained in paragraph 32 of the Complaint and further avers that the studies and articles referenced therein speak for themselves.

33. Merck denies each and every allegation set forth in paragraph 33 of the Complaint, except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx in a manner consistent with the relevant FDA-approved prescribing information until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.

34. Merck denies each and every allegation set forth in paragraph 34 of the

Complaint, except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx in a manner consistent with the relevant FDA-approved prescribing information until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.

35. Merck denies each and every allegation set forth in paragraph 35 of the Complaint, except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx in a manner consistent with the relevant FDA-approved prescribing information until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.

36. Merck denies each and every allegation contained in paragraph 36 of the Complaint and further avers that the studies and articles referenced therein speak for themselves.

37. Merck denies each and every allegation contained in paragraph 37 of the Complaint.

38. Merck denies each and every allegation contained in paragraph 38 of the Complaint and further avers that the studies and articles referenced therein speak for themselves.

39. Merck denies each and every allegation contained in paragraph 39 of the Complaint and further avers that the studies and articles referenced therein speak for themselves.

40. Merck denies each and every allegation contained in paragraph 40 of the Complaint.

41. Merck denies each and every allegation contained in paragraph 41 of the Complaint.

42. Merck denies each and every allegation contained in paragraph 42 of the Complaint and further avers that the studies and articles referenced therein speak for themselves.

43. Merck denies each and every allegation contained in paragraph 43 of the Complaint and further avers that the studies and articles referenced therein speak for themselves.

44. Merck denies each and every allegation contained in paragraph 44 of the Complaint and further avers that the studies and articles referenced therein speak for themselves.

45. Merck denies each and every allegation set forth in paragraph 45 of the Complaint and avers that on September 30, 2004, Merck announced that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking Vioxx compared with those taking placebo. Merck further avers that given the availability of alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of Vioxx best served the interests of patients.

46. Merck denies each and every allegation contained in paragraph 46 of the Complaint except admits that Merck has had product discussions with health care professionals through, *inter alia*, its Professional Representatives.

47. Merck denies each and every allegation contained in paragraph 47 of the Complaint except admits that Merck has had product discussions with health care professionals through, *inter alia*, its Professional Representatives.

48. Merck denies each and every allegation contained in paragraph 48 of the Complaint except admits that Merck has had product discussions with health care professionals through, *inter alia*, its Professional Representatives.

49. Merck denies each and every allegation contained in paragraph 49 of the Complaint.

50. Merck denies each and every allegation contained in paragraph 50 of the Complaint.

51. Merck denies each and every allegation contained in paragraph 51 of the Complaint.

52. Merck denies each and every allegation contained in paragraph 52 of the Complaint.

53. Merck denies each and every allegation contained in paragraph 53 of the Complaint and further avers that the studies and articles referenced therein speak for themselves.

54. Merck denies each and every allegation contained in paragraph 54 of the Complaint and further avers that the studies referenced therein speak for themselves.

55. Merck denies each and every allegation contained in paragraph 55 of the Complaint and further avers that the studies and articles referenced therein speak for themselves.

56. Merck denies each and every allegation contained in paragraph 56 of the Complaint.

57. Merck denies each and every allegation contained in paragraph 57 of the Complaint except admits that Plaintiffs bring this action and purport to seek monetary damages but denies that there is any legal or factual basis for such relief.

58. Merck denies each and every allegation contained in paragraph 58 of the Complaint.

Response to "PLAINTIFFS CLAIMS FOR RELIEF"

COUNT I

PRODUCTS LIABILITY UNDER AEMLD AND STRICT LIABILITY PURSUANT TO

§402A OF THE RESTATEMENT (SECOND) OF TORTS"

59. With respect to the allegations contained in paragraph 59 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 39 of this Answer with the same force and effect as though set forth here in full.

60. Merck denies each and every allegation contained in paragraph 60 of the Complaint except that it admits that it manufactured, marketed and distributed the prescription medicine Vioxx and that it marketed and distributed Vioxx in Alabama.

61. Merck denies each and every allegation contained in paragraph 61 of the Complaint except that it admits that it manufactured, marketed and distributed the prescription medicine Vioxx.

62. Merck denies each and every allegation contained in paragraph 62 of the Complaint except that it admits that it manufactured, marketed and distributed the prescription medicine Vioxx.

63. Merck denies each and every allegation contained in paragraph 63 of the Complaint except that it admits that it manufactured, marketed and distributed the prescription medicine Vioxx.

64. Merck denies each and every allegation contained in paragraph 64 of the Complaint except that it admits that it manufactured, marketed and distributed the prescription medicine Vioxx.

65. Merck denies each and every allegation contained in paragraph 65 of the Complaint except that it admits that it manufactured, marketed and distributed the prescription medicine Vioxx.

66. Merck denies each and every allegation contained in paragraph 66 of the Complaint except that it admits that it manufactured, marketed and distributed the prescription medicine Vioxx. Merck admits that Plaintiffs bring this action and purports to seek monetary damages but denies that there is any legal or factual basis for such relief.

67. Merck denies each and every allegation contained in paragraph 67 of the Complaint.

68. Merck denies each and every allegation contained in paragraph 68 of the Complaint.

69. Merck denies each and every allegation contained in paragraph 69 of the Complaint.

Response to COUNT II

NEGLIGENCE AND WANTONNESS

70. With respect to the allegations contained in paragraph 70 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 69 of this Answer with the same force and effect as though set forth here in full.

71. The allegations contained in paragraph 71 are legal conclusions as to which no responsive pleading is required. If a response is required, Merck denies the allegations made in this paragraph of the Complaint.

72. Merck denies each and every allegation contained in paragraph 72 of the Complaint.

73. Merck denies each and every allegation contained in paragraph 73 of the Complaint except admits that Plaintiffs bring this action and purports to seek monetary damages but denies that there is any legal or factual basis for such relief.

Response to COUNT III

NEGLIGENCE PER SE

74. With respect to the allegations contained in paragraph 74 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 73 of this Answer with the same force and effect as though set forth here in full.

75. The allegations contained in paragraph 75 are legal conclusions as to which no responsive pleading is required. If a response is required, Merck denies the allegations made in this paragraph of the Complaint.

76. Merck denies each and every allegation contained in paragraph 76 of the Complaint.

77. Merck denies each and every allegation contained in paragraph 77 of the Complaint.

78. Merck denies each and every allegation contained in paragraph 78 of the Complaint.

79. Merck denies each and every allegation contained in paragraph 79 of the Complaint.

80. Merck denies each and every allegation contained in paragraph 80 of the Complaint.

81. Merck denies each and every allegation contained in paragraph 81 of the Complaint.

82. Merck denies each and every allegation contained in paragraph 82 of the Complaint.

83. Merck denies each and every allegation contained in paragraph 83 of the Complaint.

84. Merck denies each and every allegation contained in paragraph 84 of the Complaint.

Response to COUNT IV

UNJUST ENRICHMENT

85. With respect to the allegations contained in paragraph 85 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 84 of this Answer with the same force and effect as though set forth here in full.

86. Merck denies each and every allegation contained in paragraph 86 of the Complaint.

Response to COUNT V

BREACH OF EXPRESS WARRANTY

87. With respect to the allegations contained in paragraph 87 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 86 of this Answer with the same force and effect as though set forth here in full.

88. The allegations contained in paragraph 88 are legal conclusions as to which no responsive pleading is required. If a response is required, Merck denies the allegations made in this paragraph of the Complaint.

89. Merck denies each and every allegation contained in paragraph 89 of the Complaint.

90. Merck denies each and every allegation contained in paragraph 90 of the Complaint except admits that Plaintiffs bring this action and purports to seek monetary damages but denies that there is any legal or factual basis for such relief.

Response to COUNT VI

BREACH OF IMPLIED WARRANTY

91. With respect to the allegations contained in paragraph 91 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 90 of this Answer with the same force and effect as though set forth here in full.

92. The allegations contained in paragraph 92 are legal conclusions as to which no responsive pleading is required. If a response is required, Merck denies the allegations made in this paragraph of the Complaint.

93. Merck denies each and every allegation contained in paragraph 93 of the Complaint.

94. Merck denies each and every allegation contained in paragraph 94 of the Complaint.

95. Merck denies each and every allegation contained in paragraph 95 of the Complaint except admits that Plaintiffs bring this action and purports to seek monetary damages but denies that there is any legal or factual basis for such relief.

Response to COUNT VII

CORPORATE RESPONSIBILITY:

JOINT VENTURES, PARENT/SUBSIDIARIES,

AND/OR SUCCESSOR CORPORATION

96. With respect to the allegations contained in paragraph 96 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 95 of this Answer with the same force and effect as though set forth here in full.

97. Merck denies each and every allegation contained in paragraph 97 of the Complaint.

98. Merck denies each and every allegation contained in paragraph 98 of the Complaint.

99. Merck denies each and every allegation contained in paragraph 99 of the Complaint.

100. Merck denies each and every allegation contained in paragraph 100 of the Complaint.

Response to COUNT VIII

CIVIL CONSPIRACY

101. With respect to the allegations contained in paragraph 101 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 100 of this Answer with the same force and effect as though set forth here in full.

102. Merck denies each and every allegation contained in paragraph 102 of the Complaint.

Response to COUNT IX

FRAUD AND DECEIT

103. With respect to the allegations contained in paragraph 103 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 102 of this Answer with the same force and effect as though set forth here in full.

104. Merck denies each and every allegation contained in paragraph 104 of the Complaint.

105. Merck denies each and every allegation contained in paragraph 105 of the Complaint except admits that it voluntarily withdrew Vioxx from the market on September 30, 2004.

106. Merck denies each and every allegation contained in paragraph 106 of the Complaint.

107. Merck denies each and every allegation contained in paragraph 107 of the Complaint.

108. Merck denies each and every allegation contained in paragraph 108 of the Complaint.

109. Merck denies each and every allegation contained in paragraph 109 of the Complaint.

110. Merck denies each and every allegation contained in paragraph 110 of the Complaint.

111. Merck denies each and every allegation contained in paragraph 111 of the Complaint.

112. Merck denies each and every allegation contained in paragraph 112 of the Complaint.

113. Merck denies each and every allegation contained in paragraph 113 of the Complaint.

114. Merck denies each and every allegation contained in paragraph 114 of the Complaint.

115. Merck denies each and every allegation contained in paragraph 115 of the Complaint.

116. Merck denies each and every allegation contained in paragraph 116 of the Complaint.

117. Merck denies each and every allegation contained in paragraph 117 of the Complaint.

118. Merck denies each and every allegation contained in paragraph 118 of the Complaint except that it admits that it manufactured, marketed and distributed the prescription medicine Vioxx.

119. Merck denies each and every allegation contained in paragraph 119 of the Complaint except that it admits that it manufactured, marketed and distributed the prescription medicine Vioxx.

120. Merck denies each and every allegation contained in paragraph 120 of the Complaint except admits that it voluntarily withdrew Vioxx from the market on September 30, 2004.

121. Merck denies each and every allegation contained in paragraph 121 of the Complaint except admits that Merck has product discussions with health care professionals through, *inter alia*, its Professional Representatives.

122. Merck denies each and every allegation contained in paragraph 122 of the Complaint.

123. Merck denies each and every allegation contained in paragraph 123 of the Complaint.

124. Merck denies each and every allegation contained in paragraph 124 of the Complaint.

125. Merck denies each and every allegation contained in paragraph 125 of the Complaint.

126. Merck denies each and every allegation contained in paragraph 126 of the Complaint.

127. Merck denies each and every allegation contained in paragraph 127 of the Complaint.

128. Merck denies each and every allegation contained in paragraph 128 of the Complaint.

129. Merck denies each and every allegation contained in paragraph 129 of the Complaint.

130. Merck denies each and every allegation contained in paragraph 130 of the Complaint.

131. Merck denies each and every allegation contained in paragraph 131 of the Complaint.

132. Merck denies each and every allegation contained in paragraph 132 of the Complaint.

133. Merck denies each and every allegation contained in paragraph 133 of the Complaint.

134. Merck denies each and every allegation contained in paragraph 134 of the Complaint and further avers that the articles referenced therein speak for themselves.

135. Merck denies each and every allegation contained in paragraph 135 of the Complaint.

136. Merck denies each and every allegation contained in paragraph 136 of the Complaint.

137. Merck denies each and every allegation contained in paragraph 137 of the Complaint except admits that Plaintiff brings this action and purports to seek monetary damages but denies that there is any legal or factual basis for such relief.

In response to the “**WHEREFORE**” paragraph of the Complaint, Merck denies each and every allegation except admits that Plaintiff brings this action and purports to seek monetary damages but denies that there is any legal or factual basis for such relief.

GENERAL MATTERS

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery in this action.

Merck incorporates any applicable defense or other defense asserted by any other defendant in this action. Merck will rely on all defenses that may become available during discovery or trial.

GENERAL AFFIRMATIVE DEFENSES

- (1) The claims of Plaintiffs may be time-barred, in whole or in part, under applicable statutes of limitations, statutes of repose, or are otherwise untimely.
- (2) The Complaint fails to state a claim upon which relief can be granted.
- (3) The claims of the Plaintiffs may be barred, in whole or in part, from recovery because they have made statements or taken actions that preclude them from asserting claims or constitute a waiver of their claims.
- (4) The claims of the Plaintiffs may be barred, in whole or in part, from recovery because of res judicata effect of prior judgments.
- (5) Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.
- (6) If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.
- (7) To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.
- (8) To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn plaintiffs directly of alleged dangers associated with the use of Vioxx, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.
- (9) If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff knowingly, voluntarily, and willfully

assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured by Merck or other manufacturer.

(10) If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

(11) If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiffs' misuse or abuse of Vioxx.

(12) If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

(13) To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

(14) To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under Alabama law.

(15) Plaintiffs' claims of fraud are barred by reason of Plaintiffs' failure to allege the circumstances constituting fraud with particularity, as required by Alabama Rules of Civil Procedure and Federal Rules of Civil Procedure Rule 9(b).

(16) Plaintiffs' claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

(17) Plaintiffs' claims are barred in whole or in part by the First Amendment.

(18) Plaintiffs' claims are barred in whole or in part because the produce at issue was made in accordance with the state of the art at the time it was manufactured.

(19) There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

(20) This case is more appropriately brought in a different venue.

(21) The claims of Plaintiffs may be barred, in whole or in part, from recovery by release as to their claims.

(22) Venue in this case is improper.

(23) The claims of Plaintiffs may be barred, in whole and in part, by the doctrine of laches.

(24) The claims of Plaintiffs are barred, in whole or in part, by their failure to mitigate damages.

(25) To the extent there were any risks associated with the use of the produce which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

(26) The claims of Plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence.

(27) The claims of Plaintiffs are barred, in whole or in part, by the governing state laws.

(28) Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

(29) Plaintiffs have not sustained any injury or damages compensable at law.

(30) Merck reserves its right to dismiss the Complaint and seek further relief for Plaintiffs failure to provide it with due process of law.

(31) To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

(32) To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of punitive damages is barred.

(33) Plaintiffs' demand for punitive damages is barred because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

(34) To the extent Plaintiffs' claim may invoke punitive damages, it violates the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments of the Constitution of the United States, on the following grounds:

(a) It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil Defendant upon the Plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) The procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple

Defendants for different alleged acts of wrongdoing, which infringes the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

(c) The procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution. *See Pacific Mut. Life Ins. Co. v. Haslip*, 111 S. Ct. 1032, 113 L. Ed. 2d 1.

(d) The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(e) The procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts and, thus, violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and,

(h) The Retroactive application of punitive damages violates the contracts clause of the United States Constitution, Article I, Section 10.

(i) The Plaintiffs' claim of punitive damages violates the due process clause of Article I, Section 13 of the Constitution of Alabama, on the following grounds:

(1) It is a violation of the due process clause to impose punitive damages which are penal in nature, upon a civil Defendant upon the Plaintiffs satisfying a burden of proof less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(2) The procedures pursuant to which punitive damages are awarded fail to provide a limit on the amount of the award against these defendants;

(3) The procedures pursuant to which punitive damages are awarded are unconstitutionally vague;

(4) The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages; and,

(5) The award of the punitive damages in this case constituted a deprivation of property without due process of law.

(j) The Plaintiffs attempt to impose punitive or extra-contractual damages on this defendant, on the basis of vicarious liability for the conduct of others, violates the Fifth and Fourteenth Amendments of the United States Constitution.

(k) The award of punitive damages to the Plaintiffs in this action would constitute a deprivation of property without due process of law required under the Fifth and Fourteenth Amendments of the United States Constitution.

(l) The procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine in violation of Article I, Section 15, of the Constitution of Alabama.

(m) The award of punitive damages against this defendant in this action would violate the prohibition against laws that impair the obligations of contracts in violation of Article I, Section 22 of the Constitution of Alabama.

(n) The procedures pursuant to which punitive damages are awarded are vague and unpredictable such that they violate the defendant's right to defend itself pursuant to Article I, Section 10 of the Constitution of Alabama.

(o) The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the amount established by the legislature under Ala. Code, Section 27-1-17 (1975), in violation of the Due Process Clause of the Fifth and Fourteenth Amendments of the U. S. Constitution and Article, Section 6, of the Alabama Constitution.

(35) The Complaint seeks to make Merck liable for punitive damages. The United States Supreme Court has reversed the Alabama Supreme Court in the case styled *BMW of North America, Inc. v. Gore*, 116 S.Ct. 1589 (1996) on the issue of punitive damages. Merck adopts by reference the defenses, criteria, limitations, and standards mandated by the United States

Supreme Court decision in that case and in *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), and any subsequent applicable decisions.

(36) Merck affirmatively pleads that any punitive damages that the Plaintiff may recover in this case should be capped in keeping with Alabama Code Section 6-11-21 and in the spirit of the Alabama Supreme Court's recent decision in *Oliver v. Towns*, 738 So. 2d 798 (Ala. 1999).

(37) The demand for punitive damages in the instant case is subject to the limitations established by the Alabama legislature and set forth in Ala. Code §6-11-21, (1975). The Alabama Supreme Court's action in abolishing the legislatively created cap on punitive damages was unconstitutional and is without effect. Under the Constitutions of the United States and the State of Alabama, the Alabama Supreme Court cannot abolish the cap created by the legislature on punitive damages through this judicial decision. *See Honda Motor Company, Ltd. v. Oberg*, 512 U.S. 415, 114 S. Ct. 2331, 2340 n.9 (1994).

(38) Merck avers that the punitive damage cap set out in Ala. Code §6-11-21, (1975) applies to the instant case. *See Horton Homes, Inc. v. Brooks*, 2001 WL 1520623 (Ala. Nov. 30, 2001).

(39) Merck avers that the punitive damages award is subject to limitation based on harm that has occurred and harm that is likely to occur. *See TXO Production Corp. v. Alliance Resources Corp.* 113 S. Ct. 2711 (US 1993).

(40) Merck avers that the method of imposing punitive damages violates Amendment 328, Section 6.11, which prohibits the use of a procedural rule to abridge, enlarge or modify the

substantive right of any party. *See Leonard v. Terminix Intern. Co., L.P.* 854 So.2d 529 (Ala. 2002).

(41) The imposition of punitive damages is an act of policy making on the part of the judiciary, in violation of Article III, Section 43 of the Constitution of Alabama.

(42) Merck adopts the terms of any applicable legislative act or Alabama Supreme Court decision which now or hereafter precludes punitive damages or limits the amount of punitive damages that can be recovered in an action at law in Alabama.

(43) Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

(44) Plaintiffs' claims are barred in whole or in part because Merck provided adequate "directions or warnings" to the use of Vioxx and any other drug or pharmaceutical preparation Plaintiffs allege to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

(45) Plaintiffs' claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

(46) Plaintiffs' claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

(47) To the extent that Plaintiffs rely upon any theory of breach of warranty, such claims are barred for lack of timely notice of breach and/or lack of privity and/or because the alleged warranties were disclaimed.

(48) Plaintiffs' claims are barred, in whole or in part, because Plaintiffs lack capacity and/or standing to bring such claim.

(49) Merck hereby gives notice that it intends to rely upon such other defenses as may become available or appear during discovery proceeding in this case or that are included in the master answer to be filed in the Multidistrict Litigation proceeding before Judge Fallon of the Eastern District of Louisiana. Merck hereby reserves the right to amend its answer to assert any such defense.

(50) If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured plaintiffs.

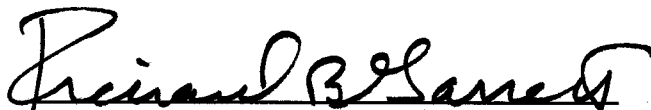
(51) The individual defendants are improperly joined.

(52) Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, it reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action. Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable costs and disbursements, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

A handwritten signature in black ink, appearing to read "Richard B. Garrett", is written over a horizontal line.

Richard B. Garrett
One of the Attorneys for Defendant,
Merck & Co., Inc.

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CERTIFICATE OF SERVICE

I hereby certify that I have served the above and foregoing document upon all interested parties by placing a copy of same in the United States Mail, postage prepaid and properly addressed on this the 30th day of October 2006, as follows:

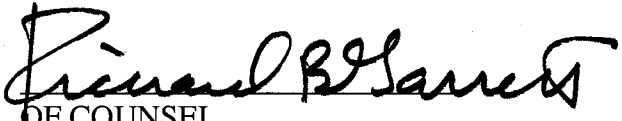
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